



Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director



Jeremiah W. (Jay) Nixon
Governor

August 25, 2010

Dear Vaccines for Children (VFC) Provider:

Subject: 2010-2011 Influenza (Flu) Order and Accountability Information/Instructions

This mailing contains the following forms for the 2010-2011 Influenza Season:

- 2010-2011 Missouri VFC Influenza Vaccine Order Form
- 2010-2011 Missouri VFC Influenza Tally Sheet (Private Providers and Local Public Health Agencies (LPHAs) For Optional Use)
- Flow Chart – Number of 2010-2011 Seasonal Influenza Vaccine doses recommended for children
- Inactivated Influenza Vaccine Information Statement
- Live, Intranasal Influenza Vaccine Information Statement

You **MUST** complete the order form titled **2010-2011 Missouri VFC Influenza Vaccine Order Form in order** to receive flu vaccine, even if you previously submitted a vaccine pre-order. Your pre-order advises us of your intent to order, but it is not an actual order. Please assure your **pin number** is included on **all** documents submitted to the VFC program.

The Advisory Committee on Immunization Practices (ACIP) recommends beginning vaccination as soon as flu vaccine is available. Please review your anticipated needs and order the number of doses you will need for a 4-6 week supply. Orders may be placed up to the amount of vaccine that was indicated on your pre-order. Seasonal flu vaccines are allocated by the Centers for Disease Control and Prevention (CDC). Your vaccine order may need to be adjusted by the VFC program to accommodate supply limitations.

The **2010-2011 Flu Accountability** will be counted on the monthly Vaccine Accountability form (revision date 4-10) for both private providers and local public health agencies. We provided you with a separate flu tally sheet, which is optional, that indicates the actual vaccine by name, type, and presentation. This was requested by several providers for accountability use this year and as a tool for projecting their vaccine needs for the next flu season. If you choose to use this form, you will:

- complete the information across the row for each patient and place a check mark under the flu presentation utilized
- total the number of doses in each column down to the bottom of the page; then
- total the doses across the bottom row for the total of all shots on the page.
- if more than one sheet used add the total for each page for the grand total

www.dhss.mo.gov

Healthy Missourians for life.

The Missouri Department of Health and Senior Services will be the leader in promoting, protecting and partnering for health.

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER: Services provided on a nondiscriminatory basis.

- the grand total is entered on the monthly Vaccine Accountability sheet Doses Administered line in the column for Pediatric flu along with all other vaccines administered during the month.

Or, you may choose to use the Vaccine Accountability Tally Sheet (revision date 4-10).

All VFC forms are available on our website www.mo.gov/Immunizations/ProviderForms.html. Additionally, we placed this letter and the attachments on our website. The documents are titled “2010-2011 Flu Packet” and are located at www.dhss.mo.gov/Immunizations on the front page and in “What’s New”.

An area of confusion this year deals with the number of doses recommended for seasonal flu for children aged 6 months through 8 years. The answer depends upon whether or not the child has received H1N1, previous seasonal flu or nothing previously. Please refer to the flow chart included in this mailing to determine the appropriate number of doses to administer. Additionally, please note that Afluria (*Merck/CSL*) in 0.5mL pre-filled syringes is **only** to be administered to those ages 8 through 18 years.

Influenza ACIP Recommendations can be found at: <http://www.cdc.gov/flu>. Foreign language Vaccine Information Statements can be found at www.immunize.org/vis.

Flu vaccines are packaged separately, therefore, they will ship separately from other vaccines ordered at the same time.

Please remember that vaccine that contains mercury (thimerosal) as a preservative may NOT be given to knowingly pregnant women or children less than 3 years of age. Section 191.235 RS Mo.

If you have questions please contact the VFC Program at 1-800-219-3224.

Sincerely,



Charlotte Sims Higgins, Coordinator
Vaccines for Children Program

CSH

Enclosures

Number of 2010-2011 Seasonal Influenza Vaccine Doses Recommended for Children

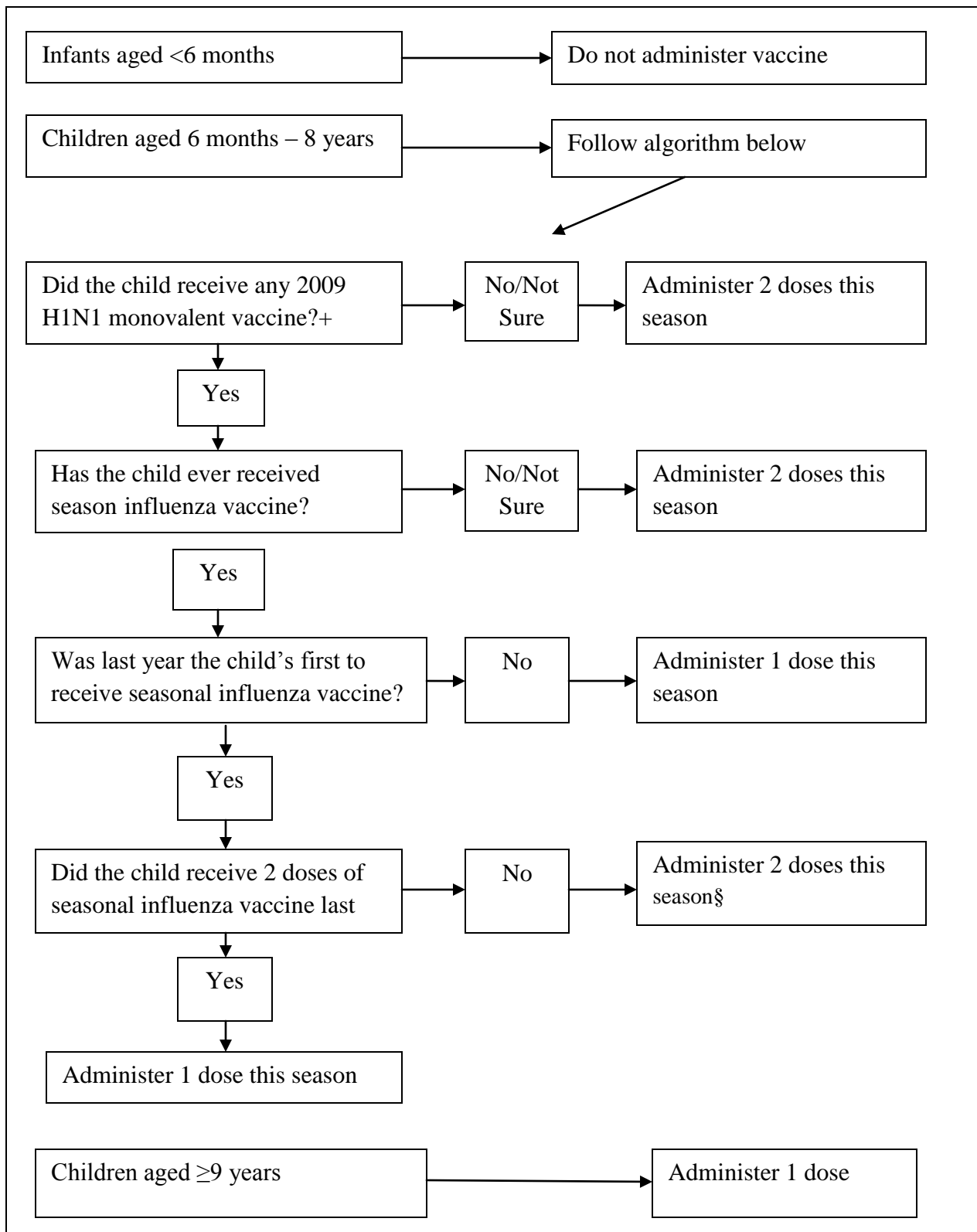


Figure developed by CDC with the American Academy of Pediatrics, Committee on Infectious Diseases
 +Children who had a laboratory-confirmed 2009 pandemic H1N1 virus infection (e.g., reverse transcription-polymerase chain reaction or virus culture specific for 2009 pandemic influenza A (H1N1) virus) are likely to be immune to this virus. At provider discretion, these children can have a “Yes” entered at this box, and proceed down the path to the next box to determine whether two doses are indicated based on seasonal vaccine history. However, if no test result is available and no influenza A (H1N1) 2009 monovalent vaccine was administered, enter “no” here.
 §Interval between 2 doses is ≥ 4 weeks

2010-2011 Missouri VFC Influenza Vaccine Order Form

INSTRUCTIONS: Please use this form to order influenza vaccine. Indicate the **number of doses** needed. You must account for all previously shipped vaccine and wastage on the monthly accountability form. Orders are allowed based on the vaccine pre-order that was submitted in the spring 2010, and the inventory requested should be for a 4-6 week supply. Providers who pre-ordered Afluria 0.25 mL prefilled syringes and Afluria 5 mL multi dose vaccine should order Fluzone vaccine as a replacement.

Vaccine	Age Information	Brand & Manufacturer	CPT Code	Packaging	Doses Ordered
Influenza Preservative Free Injectable	Ages 6-35 months only	Fluzone (<i>Sanofi</i>)	90655SL	0.25 mL prefilled syringes- 10 per box NDC# 49281-0010-25	
	Ages 3 through 18 years	Fluarix (<i>GSK</i>)	90656SL	0.5 mL prefilled syringes- 10 per box NDC# 58160-0877-46	
		Fluzone (<i>Sanofi</i>)	90656SL	0.5 mL prefilled syringes- 5 per box NDC# 49281-0010-50	
		Fluzone (<i>Sanofi</i>)	90656SL	0.5 mL single-dose vials- 10 per box NDC# 49281-0010-10	
	Ages 4 through 18 years	Fluvirin (<i>Novartis</i>)	90656SL	0.5 mL prefilled syringes- 10 per box NDC# 66521-0113-02	
	Ages 8 through 18 years	Afluria (<i>Merck/CSL</i>)	90656SL	0.5mL pre-filled syringes- 10 per box NDC# 33332-0010-01	
Influenza Preservative Containing Injectable (These vaccines cannot be administered to children less than 3 years of age or knowingly pregnant women) Section 191.235 RS Mo	Ages 3 through 18 years	Fluzone (<i>Sanofi</i>)	90658SL	5 mL multi-dose vial- 10 doses per vial NDC# 49281-0386-15	
	Ages 4 through 18 years	Fluvirin (<i>Novartis</i>)	90658SL	5 mL multi-dose vial- 10 doses per vial NDC# 66521-0113-10	
Influenza Preservative Free Intranasal	Healthy children ages 2 through 18 years	FluMist (<i>MedImmune</i>)	90660SL	0.2mL nasal sprayer- 10 per box NDC#66019-0108-10	

SIGNATURE and DATE



VFC use only

Please assure that your address and pin number are provided below:

RETURN COMPLETED ORDER FORM TO:
Vaccines for Children Program, MODHSS
PO Box 570, Jefferson City, MO 65102
Phone: 800-219-3224 FAX: 573-526-5220

INACTIVATED INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2010-11

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Other illnesses can have the same symptoms and are often mistaken for influenza.

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

By getting vaccinated you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, or the “flu shot” is given by injection into the muscle.
2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A “high-dose” inactivated influenza vaccine is available for people 65 years of age and older. Ask your healthcare provider for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year.

The 2010-2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses – influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your healthcare provider for more information.

3 Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

WHEN

Getting the vaccine as soon as it is available will provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from November through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your healthcare provider.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

4 Some people should not get inactivated influenza vaccine or should wait

- Tell your healthcare provider if you have any **severe** (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.

- Influenza vaccine virus is grown in eggs. People with a **severe egg allergy** should not get influenza vaccine.
- A severe allergy to any vaccine component is also a reason not to get the vaccine.
- If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

- Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider will help you decide whether the vaccine is recommended for you.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your healthcare provider about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever • aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Ask your healthcare provider for more information.

The safety of vaccines is always being monitored. For more information, visit:

www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and
www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your healthcare provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/flu



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (8/10/10) 42 U.S.C. §300aa-26

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2010-11

Vaccine Information Statements are available in Spanish and many other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms lasts only a few days. They include:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Other illnesses can have the same symptoms and are often mistaken for influenza.

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Influenza can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

By getting vaccinated you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:

1. **Live, attenuated** influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.
2. **Inactivated** (killed) influenza vaccine, or the “flu shot,” is given by injection into the muscle. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year.

The 2010 – 2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses– influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts about a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people **2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below).

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

4 Some people should not receive LAIV

LAIV is not recommended for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- **Adults 50 years of age and older or children from 6 through 23 months of age.** (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women.
- People who have long-term health problems with:
 - heart disease
 - kidney or liver disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). *Close contacts of other people with a weakened immune system (such as those with HIV) **may** receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.*
- Children or adolescents on long-term aspirin treatment.

Tell your healthcare provider if you have any severe (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.

- Influenza vaccine virus is grown in eggs. People with a **severe egg allergy** should not get influenza vaccine.
- A severe allergy to any vaccine component is also a reason not to get the vaccine.
- If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider will help you decide whether the vaccine is recommended for you.

Tell your healthcare provider if you have gotten any other vaccines in the past 4 weeks.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your healthcare provider about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I receive influenza vaccine?

Getting the vaccine as soon as it is available will provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur any time, but most influenza occurs from November through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your healthcare provider.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.

- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:

www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html
and

www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

9 How can I learn more?

- Ask your healthcare provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/flu



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Live, Attenuated Influenza Vaccine (8/10/10) U.S.C. §300aa-26